

Docket No. 4026-4002US1

**REMARKS**

Reconsideration of this application as amended is respectfully requested.

Applicants express their appreciation for the courtesy extended to Applicants' representative, Sanford T. Colb, during an interview with the Examiner on January 6, 2004. The substance of the interview is set forth in the Interview Summary, Paper No. 9. During the interview, agreement was reached that the Claim 44 as amended herein defines patentable subject matter over the prior art of record. Applicants were requested to present the amendments to Claim 44 in a Request For Continued Examination.

The prior Office Action's indication that Claims 26-43 and 46 are allowed is gratefully acknowledged. Applicants believe the amendments to Claim 44 presented herein are fully responsive to all points of rejection raised by the Examiner, and place the application in condition for allowance.

**Claim amendments**

Claim 44 has been amended to recite that the breath analyzer is a capnographic breath analyzer, and to recite the indication provided by the claimed apparatus as the respiratory clinical state of the subject. Support for this recitation is found in the specification on page 2, in the first paragraph of the Summary of the Invention.

**Claim rejections - 35 USC § 102**

Former Claims 44 and 45 have been rejected under 35 USC § 102(e) as being anticipated by US 6,306,088 to Krausman et al. The Office Action argued that "Krausman discloses an apparatus comprising a breath receiver 23 in fluid communication with a subject, and a breath analyzer and respiration diagnosis generator (external computer 17). The external

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computer 17 also receives input from non-breath related measuring units 11, where the units may include a pulse oximetry unit or an ECG recording unit. From the breath receiver signal, the computer 17 may determine and display airflow rate from the breath receiver signal. Additionally, the computer 17 identifies sleep disorder breathing events from all the input signals, and characterizes them as being central, obstructive, or mixed, and as apnea or hypnopeas (Figs. 4-10)." Office Action dated October 8, 2003, page 2.

However, Krausman describes an apparatus that identifies sleep disorder breathing events, which are characterized as being central, obstructive, or mixed, and as apnea or hypnopeas. All of these characterizations are based on the overall breathing performance of the subject, as indicated, for instance, by the measured airflow, or by the thorax or abdominal motion or respiration effort. Nowhere does Krausman teach or suggest analysis of the breath content, such as by means of a capnographic measurement, to determine the level of carbon dioxide in the subject's exhaled breath. Such capnographic measurements provide the physician, *inter alia*, with information about the perfusion performance of the subject's lungs, which enable diagnoses to be made about the ability of the lungs to fulfil their primary function, namely that of keeping the blood flow supplied with oxygen, and of eliminating the bodies metabolic combustion products

Though the Office Action argues the sleep disorder breathing events provide indications of the respiratory status of the subject, Applicants respectfully submit that such measurements could not reasonably be described as providing information about the respiratory clinical state of the subject. Such a state requires measurements and provide information at a far more basic level than those for the sleep apnea disorders described by Krausman, where the analysis is used for determination of a breathing phenomenon, rather than a basic pulmonary clinical state.

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In contrast to what is described by Krausman, amended Claim 44 of the present application now recites;

Apparatus for computerized breath analysis comprising:

a breath receiver in fluid communication with a subject;

a capnographic breath analyzer coupled to said breath receiver which analyzes at least one breath of the subject for its carbon dioxide content and provides at least one output;

a respiration diagnosis generator; and

at least one input receiving at least one non-respiratory measurement made on the subject;

wherein said respiration diagnosis generator provides an indication of the respiratory clinical state of the subject based on said at least one output and on at least one non-respiratory measurement.(Emphasis added)

Applicants respectfully submit that Krausman does not teach or suggest the elements of Claim 44 as amended and that amended Claim 44 is patentable over Krausman. Amended Claim 45 depends on amended Claim 44 and recites further patentable matter, and is therefore also allowable.

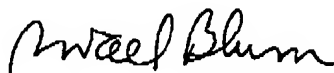
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Conclusions

For the reasons set for herein, Applicants respectfully submit that Claims 26-46, as currently presented define patentable subject matter over the prior art, and are in condition for allowance. An early allowance of this application is therefore respectfully requested.

Respectfully submitted,

Dated: March 17, 2004



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